

# 510(k) Summary of Safety and Effectiveness

## PERI-LOC® Locking Bone Plates, Locking and Non-locking Bone Screws for the Upper Extremity

<b>Submitted By:</b>	Smith & Nephew, Inc. Orthopaedic Division 1450 Brooks Road Memphis, TN 38116	<b>JUN - 8 2006</b>
<b>Date:</b>	May 12, 2006	
<b>Contact Person:</b>	David Henley, Senior Regulatory Affairs Specialist Tel: (901) 399-6487 Fax: (901) 399-1557	
<b>Proprietary Name:</b>	<b>PERI-LOC® Periarticular Locked Plating System - Locking Bone Plates &amp; Screws for the Upper Extremity</b>	
<b>Common Name:</b>	Bone Plates and Bone Screws	
<b>Classification Name and Reference:</b>	21 CFR 888.3030, single/multiple component metallic bone fixation appliances and accessories - Class II 21 CFR 888.3040, smooth or threaded metallic bone fixation fastener - Class II	
<b>Device Product Code and Panel Code:</b>	HRS, HWC, KTT, LXT / Orthopedics / 87	

### Device Description:

The subject devices include PERI-LOC® Periarticular Locking Bone Plates, Locking and Non-locking Bone Screws, which are *line additions to and modifications to* the PERI-LOC® Periarticular Locked Plating System devices previously cleared under K051735. Like the predicate devices listed below, the subject components include various sizes of contoured, locking bone plates, locking and non-locking bone screws made from stainless steel. PERI-LOC® locking bone plates and locking bone screws incorporate a screw-to-plate locking feature which forms a locked, fixed angle construct to aid in holding fracture reduction.

### Intended Use:

The PERI-LOC® Periarticular Locked Plating System can be used for adult and pediatric patients, as well as patients with osteopenic bone. PERI-LOC® bone plates and screws are indicated for fixation of pelvic, small and long bone fractures, including those of the tibia, fibula, femur, pelvis, acetabulum, metacarpals, metatarsals, humerus, ulna, radius, calcaneus, and clavicle.

### Technological Characteristics:

Components comprising PERI-LOC® Locking Bone Plates, Locking and Non-locking Bone Screws for the Upper Extremity are very similar to legally marketed devices listed below in that they share identical indications for use (compared to K051735), are manufactured from identical material, and incorporate very similar technological characteristics.

### Substantial Equivalence Information:

When compared to the predicate devices listed below, substantial equivalence is based on similarities with regard to overall indications for use, material composition, and technological design characteristics.

- Smith & Nephew Locked Plating System (PERI-LOC® Periarticular Locked Plating System) – K033669
- PERI-LOC® Periarticular Locked Plating System for the Upper Extremity – K051735



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUN - 8 2006

Mr. David Henley  
Senior Regulatory Affairs Specialist  
Smith & Nephew, Inc.  
Orthopaedic Division  
1450 Brooks Road  
Memphis, Tennessee 38116

Re: K061352  
Trade/Device Name: PERI-LOC Periarticular Locked Plating System  
Regulation Number: 21 CFR 888.3030  
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories  
Regulatory Class: Class II  
Product Codes: HRS, HWC, KTT, LXT  
Dated: May 12, 2006  
Received: May 15, 2006

Dear Mr. Henley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

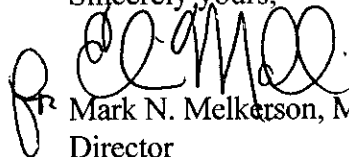
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkersen". The signature is written in a cursive, flowing style. To the left of the signature is a small, stylized initial or mark.

Mark N. Melkersen, M.S.

Director

Division of General, Restorative and  
Neurological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Premarket Notification  
Indications for Use Statement

510(k) Number (if known): K061352

Device Name: PERI-LOC<sup>®</sup> Periarticular Locked Plating System

Indications for Use:

The PERI-LOC<sup>®</sup> Periarticular Locked Plating System can be used for adult and pediatric patients, as well as patients with osteopenic bone. PERI-LOC<sup>®</sup> bone plates and screws are indicated for fixation of pelvic, small and long bone fractures, including those of the tibia, fibula, femur, pelvis, acetabulum, metacarpals, metatarsals, humerus, ulna, radius, calcaneus, and clavicle.

Components in the PERI-LOC<sup>®</sup> Periarticular Locked Plating System are for single use only.

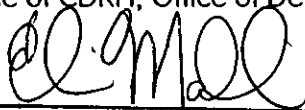
Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-the-Counter Use \_\_\_\_\_  
(Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

**Division of General, Restorative,  
and Neurological Devices**

510(k) Number K061352